1 2 3 4 5 6 7 8 9 10	Richard G. McCracken (Nevada Bar No. 274 Paul L. More (Nevada Bar No. 9628) Sarah Grossman-Swenson (Nevada Bar No. McCRACKEN, STEMERMAN & HOLSBER 1630 Commerce Street, Suite A-1 Las Vegas, Nevada 89102 Tel: (702) 386-5107 Fax: (702) 386-9848 Email: rmccracken@msh.law     pmore@msh.law     sgs@msh.law  Attorneys for Culinary Health Fund	11979)
11	UNITED STATES DISTRICT COURT DISTRICT OF NEVADA	
13   14   15   16   17   18   19   20   21   22   23   24	PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; and BIOTECHNOLOGY INNOVATION ORGANIZATION,  Plaintiff,  vs.  BRIAN SANDOVAL, in his official capacity as Governor of the State of Nevada; RICHARD WHITLEY, in his official capacity as Director of the Nevada Department for Health and Human Services; and the NEVADA LEGISLATURE,  Defendants.	CULINARY HEALTH FUND'S MOTION TO INTERVENE; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO INTERVENE
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## MOTION TO INTERVENE (Fed. R. Civ. P. 24)

The Culinary Health Fund hereby moves to intervene in this lawsuit pursuant to Federal Rules of Civil Procedure 24(a) and (b) to defend the constitutionality of Senate Bill No. 539 (SB 539), 2017 Nev. Stat., ch. 592, at 4295. This motion is based on the attached Memorandum of Points and Authorities, all pleadings, documents and exhibits on file in this case, and any oral argument the Court may allow. Consistent with Federal Rule of Civil Procedure 24(c), the Fund's proposed answer to the complaint for declaratory and injunctive relief is attached as Exhibit 1. The Fund also requests leave to file its brief in opposition to plaintiffs' motion for preliminary injunction. By separate motion, the Fund seeks leave to file its opposition to the preliminary injunction motion by Monday, October 9.

# MEMORANDUM OF POINTS AND AUTHORITIES INTRODUCTION

Culinary Health Fund ("CHF" or the "Fund") moves for intervention in this lawsuit pursuant to Federal Rules of Civil Procedure 24(a) and (b) in order to defend SB 539's constitutionality. The Fund also seeks leave to file its opposition to the preliminary injunction sought by Pharmaceutical Research and Manufacturers of America ("PhRMA") and Biotechnology Innovation Organization ("BIO"). This motion is timely, the Fund has significant protectable interests in this case that would be impaired if SB 539 were declared unconstitutional, and neither the Office of the Attorney General nor the Nevada Legislature are adequately protecting the Fund's interests. To the contrary, both defendants have taken positions that would undermine key provisions of SB 539.

CHF is a multi-employer Taft-Hartley fund that provides medical, dental and vision healthcare benefits to more than 125,000 workers and their dependents in Nevada, which makes CHF one of the largest private healthcare-benefit providers in the State. The Fund is entitled to intervene to defend the constitutionality of legislation that it supported in order to bring transparency to Nevada's market for essential diabetes

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medications and, ultimately, to help protect the Fund's participants with diabetes. While Governor Sandoval has been a strong advocate for SB 539—signing the bill into law at a press conference in front of the Fund's new medical clinic—the Nevada Office of the Attorney General ("OAG") has demonstrated beyond any doubt that it will not adequately protect the Fund's interests in this litigation. Nevada's Legislative Counsel Bureau, representing the Nevada Legislature, has also moved for intervention, but has presented an interpretation of SB 539 that would eviscerate some of the law's most important provisions.

The Fund provides medical benefits to over 12,000 participants diagnosed with diabetes, and many thousands more who are pre-diabetic. (See Declaration of Bobbette Bond filed herewith at ¶¶ 4, 10.) Prescription medications for these diabetic participants are a major and increasing cost for the Fund and, ultimately, for the unionized employers and workers who contribute to it. (Id. ¶¶ 11-15.) The Fund paid approximately \$26 million for diabetes medications over the last year, which is fully one-quarter of the Fund's total prescription-drug spend. The amount that the Fund and others pay for key diabetes treatments has increased dramatically and often inexplicably in recent years. For example, the unit price for Humalin and Humalog insulin pens, manufactured by Eli Lilly, increased by 96% from September 2013 to August 2016. (Id. ¶ 14.) Glumetza—a metaformin manufactured by Valeant Pharmaceuticals that is used in the control of Type-2 diabetes—increased in unit price by more than 825% during the same time period. (Id. ¶ 15.) Ultimately, all of the Fund's participants and contributing employers pay for these price increases.

Similar trends nationally—and a growing consensus that the lack of transparency in pharmaceutical-drug pricing contributes to the unsustainable rise in market prices—has led to bipartisan federal and state efforts to mandate drug-pricing disclosure. Legislators in thirty states have passed or introduced bills that would require some form of pricing disclosure by drug manufacturers. At the federal level, Senators John McCain (R-AZ) and Tammy Baldwin (D-WI) have introduced the Fair Accountability and

Innovative Research ("FAIR") Drug Pricing Act, which would mandate disclosure of

information related to substantial price increases similar to that required under SB 539. These laws follow successful state legislation requiring other health-service providers, such as hospitals and insurers, to publish information about their pricing practices.

The Fund advocated for SB 539 in order to help bring transparency to an important part of Nevada's prescription-drug market, to the benefit of its participants and beneficiaries. Among other things, SB 539 requires diabetes drug manufacturers to disclose basic information about the pricing of their products to the Nevada Department of Health and Human Services ("DHHS") and, ultimately, to the public. If a manufacturer has increased the wholesale acquisition cost of an essential diabetes drug by more than a measure of medical inflation, it is required to explain the factors that led to that price increase. The Fund advocated for SB 539 with the expectation that mandated disclosure of this pricing information, along with the law's mandated-disclosure requirements for pharmacy benefit managers ("PBMs"), would lead to a more transparent market for diabetes medications in Nevada and, ultimately, to lower privately negotiated drug prices for the Fund and its beneficiaries.

CHF has a right to intervene in this lawsuit to defend SB 539's constitutionality. There is no question as to this motion's timeliness. It is filed at the outset of the litigation and a week after it became clear that the Office of the Attorney General could not be relied upon to defend the statute's constitutionality. *Idaho Farm Bureau Fed'n v. Babbitt,* 58 F.3d 1392, 1397 (9th Cir. 1995). The Fund and its participants have a protectable interest in the SB 539's constitutionality—an interest in access to information about drug manufacturers' pricing of essential diabetes medications—and this interest would be impaired if SB 539 were declared invalid.

The Fund has also met the "minimal" burden of demonstrating that existing parties' representation of its interests "may be" inadequate. *Sw. Ctr. for Biological Diversity v. Berg*, 268 F.3d 810, 823 (9th Cir. 2001). The Fund has a stake in this litigation that is distinct from that of the Governor, DHHS, or the Legislature because it

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is a private-sector purchaser of diabetes drugs and because, unlike the State defendants, it will rely upon SB 539's exemption of reported pricing information from Nevada's definition of a trade secret. See Citizens for Balanced Use v. Montana Wilderness Ass'n, 647 F.3d 893, 899 (9th Cir. 2011). PhRMA and BIO have made this exemption the centerpiece of their legal challenge.

While this separate, "parochial" interest is enough to show inadequacy of representation, the OAG's opposition to the plaintiffs' preliminary-injunction motion is further, conclusive proof that the Fund's interests are not protected in this lawsuit. In response to plaintiffs' twenty-four page brief, the OAG has filed a five-and-a-half page response, with only a single case citation (on a collateral point), little attempt to challenge the lawsuit's merit, and apparent (and legally unwarranted) concessions. A brief from Nevada's Legislative Counsel Bureau also tries to read key protective provisions out of the statute. Private-party intervention is necessary when the government is taking "a position that actually compromises (and potentially eviscerates) the protections" of the challenged law. California, ex rel. Bill Lockyer v. United States, 450 F.3d 436, 445 (9th Cir. 2006).

### BACKGROUND FACTS

# The Culinary Health Fund

The Fund is a Taft-Hartley multi-employer plan dedicated to providing health coverage for hotel and hospitality workers on the Las Vegas Strip, in Downtown Las Vegas and at McCarran Airport. (Bond Decl. ¶ 3.) The plan operates under collectively bargained agreements between Culinary Workers Union Local 226, the largest union in Nevada, Bartenders Local 165, IATSE Local 720, Musicians Local 369, and employer contributors to the Fund, including Boyd Gaming, Bally's, Bellagio, Caesars Palace, The Cosmopolitan of Las Vegas, The Flamingo, Fremont Hotel & Casino, Golden Nugget, Harrah's, Main Street Station Casino, MGM Grand, New York-New York, Planet Hollywood, SLS Las Vegas, and Wynn | Encore. (*Ibid.*) The Fund is financed through contributions from these participating employers, which are made at a specified rate,

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based on the hours worked by bargaining-unit employees. (*Ibid.*) It is governed by a Board of Trustees made up of union and employer representatives, including representatives of major Nevada employers like MGM, Caesars Entertainment, and Boyd Gaming Corporation. (Id. ¶ 5.)

The Fund works to provide high-quality, affordable health benefits, including medical, pharmacy, dental, and vision benefits, to more than 125,000 workers and their dependents in Nevada, which makes the Fund one of the largest private healthcare benefits providers in the State. (Id. ¶ 4.) In addition to providing these healthcare benefits, the Fund maintains its own pharmacy, known as the Culinary Pharmacy, at 1945 Las Vegas Boulevard South. (Id. ¶ 7.) The Culinary Pharmacy carries over 300 prescriptions, including most diabetic medications and supplies, and is only for eligible participants and dependents. (Ibid.) It dispenses more prescriptions than any other pharmacy in the state. (Ibid.)

In June 2017, the Fund opened a medical clinic at 650 N. Nellis Blvd. in east Las Vegas. (*Id.* ¶ 8.) The two-story building houses a full range of medical care, including adult and pediatric primary care, as well as dental, optometry and urgent cares services and a pharmacy. (*Ibid.*) The Fund expects approximately 30,000 primary care visits per year, 10,000 urgent care visits, and expects to fill approximately 250,000 prescriptions. (*Ibid.*) Governor Sandoval used the medical clinic's opening as the backdrop for signing SB 539, recognizing the Fund's key role in steering the statute to passage.¹

The Fund contracts with a third-party pharmacy benefit manager ("PBM") to assist with drug formularies, contract with pharmacies, negotiate prices and rebates with drug manufacturers, and process and pay prescription drug claims. (*Id.* ¶ 6.) As is the case with other PBM-negotiated rebates and price-reduction agreements with drug manufacturers, the Fund has little information on the portion of any rebates with drug manufacturers that its PBM is retaining and little means to compare the prices its PBM

<sup>&</sup>lt;sup>1</sup> See "Sandoval signs bill to increase insulin price transparency," LAS VEGAS REVIEW-JOURNAL, June 15, 2017, at:https://www.reviewjournal.com/news/2017-legislature/sandoval-signs-bill-to-increase-insulin-price-transparency/.

negotiates on its behalf with prices available to other insurers and healthcare benefit providers. (*Id.*  $\P\P$  16-18.)

## The Rising Cost of Diabetes Medications

Nationally, the cost of diabetes medications has increased at an alarming rate. According to a study in the Journal of the American Medical Association, the mean unit-price of all forms of insulin increased by 197% between 2002 and 2013.<sup>2</sup> The price trend of for the most prescribed forms of analog insulins is even more alarming. Since 2004, the wholesale acquisition cost for Novo Nordisk's insulin Novolog is up 381 %, Eli Lilly's Humalog is up 380 %, and Sanofi's Lantus is up 400 %, according to data from Truven Health Analytics.<sup>3</sup>

Price increases for essential diabetes medications often occur abruptly and without a clear reason. (Bond Decl. ¶ 12.) In May of this year, Eli Lilly raised its list price for Humalog by 7.8 %, to \$274.70 for a 10-milliliter vial, while Novo Nordisk increased the list price of its Novolog drug by a near-identical 7.9 %, to \$275.58 for a 10-milliliter vial. <sup>4</sup> Concerns that such "shadow pricing" of insulins—ostensible competitors raising their prices in lock-step—may in fact be evidence of price collusion have led lawsuits in several states, including *Boss et al. v. CVS Health Corporation et al.*, Case No. 17-cv-01823-BRM-LHG (D.N.J.). Such concerns also led Senator Bernie Sanders and Representative Elijah Cummings to request that the Department of Justice investigate Eli Lilly, Novo Nordisk ,and Sanofi for price collusion in setting insulin prices. In a letter to the Department of Justice, Sanders and Cummings cited 13 instances since 2009 in which the prices of

<sup>25 2</sup> Xinyang Hua, MSc; Natalie Carvalho, PhD; Michelle Tew, MPH; *et al*, "Expenditures and Prices of Antihyperglycemic Medications in the United States: 2002-2013," *JAMA*, 315(13):1400-1402 (2016).

<sup>&</sup>lt;sup>3</sup> Ben Popken, "Is Insulin the New EpiPen? Families Facing Sticker Shock Over 400 Percent Price Hike," NBC NEWS, November 2, 2016, available at: https://www.nbcnews.com/business/consumer/insulin-new-epipen-families-facing-sticker-shock-over-400-percent-n667536.

 $<sup>^4</sup>$  Lydia Ramsey, "The prices for life-saving diabetes medications have increased again," BUSINESS INSIDER, May 15, 2017, available at: http://www.businessinsider.com/insulin-prices-increased-in-2017-2017-5.

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market for long-acting, injectable insulin—were increased at the same time.<sup>5</sup>

Lantus (made by Sanofi) and Levemir (made by Novo Nordisk)—which dominate the

Prescription medication for diabetic participants is a major and increasing cost for the Fund. (*Id.* ¶ 13.) From November 2015 through October 2016, the Fund paid approximately \$26 million for participants' diabetes medications and glucose test strips, which was one-quarter of the Fund's total spending on prescription medication over that period. (*Ibid.*) UNITE HERE Health, of which Culinary Health Fund is a part, has seen a 48% increase in cost for Eli Lilly insulin from 2013 to 2016, including a 96% increase in the price of Humalin and Humalog pens, a 42% increase in the price of vials, and a 37% increase in the price of cartridges. (*Id.* ¶ 14.) From 2013-2016, UNITE HERE Health has experienced a massive increase in the price for Metaformin ER, including a 851% increase in the price of Glumetza 1000mg tabs, and a 828% increase in the price of Glumetza 500mg tabs. (*Id.* ¶ 15.) UNITE HERE Health also experienced a 1,842% increase in the price of generic Metformin 500 mg tabs from 2013 to 2016. (*Ibid.*)

These rising costs for insulin drugs put significant financial pressure on the Fund. (Id. ¶ 22.) Because most participants in the Fund are working- and middle-class Nevadans, the Fund has a mission of keeping co-pays and deductibles as low as possible. (Ibid.) The Fund's employer contributors also have a financial interest in keeping their contributions to the Fund manageable. But rising diabetes drug costs puts pressure on the Fund to increase co-pays and deductibles for all participants, and on the participating unions and employers to increase employer contributions to the Fund or cut benefits. (Ibid.)

Very little transparency exists in the market for diabetes and other prescription medications. The market for pharmaceutical drugs has complex, nontransparent financial arrangements, and limits available information in asymmetric ways that disadvantage third-party payers like the Fund and its participants.

 $<sup>^{5}</sup>$  Available at: https://www.sanders.senate.gov/download/sanders-cummings-letter-to-doj-ftc-oninsulin?inline=file

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Typically, diabetes medicines—like other prescription medications—are purchased by wholesalers from drug manufacturers, and then purchased by pharmacies (retail or mail-order) from wholesalers. At the third step in the pricing chain, drug manufacturers pay rebates to the pharmacy dispensing the drug, to the health plan, or more commonly to the PBM that acts as an agent for the health plan. The amounts of these rebates vary significantly by medication, drug manufacturer, and PBM, and are generally kept secret from healthcare plans like the Fund. Even the amount of drug-manufacturer rebates that are retained by the PBM and not shared with the health care plan is frequently kept secret. The effect is that purchasers of diabetes medications like the Fund have very little information on which to base their purchasing decisions and negotiations. Policy experts have pointed to this lack of transparency as a major factor in increasing drug prices.<sup>6</sup>

# Legislative Efforts at Pricing Transparency

This lack of pricing transparency in the pharmaceutical-drug market has led to bipartisan legislative action at both the federal and state level. Several states in addition to Nevada have recently enacted price-transparency measures, including Vermont (Vt. Stat. Ann. tit. 33, § 2010) and Maryland (HB 631). California's legislature overwhelmingly passed a drug price transparency bill (SB 17) that will require drug manufacturers to report information to the state about their price increases. According to the National Academy for State Health Policy, some 30 states across the country have drafted more than 60 drug price transparency bills designed to identify the costs that

<sup>&</sup>lt;sup>6</sup> See, e.g., Steven M. Lieberman and Paul B. Ginsburg, "Would Price Transparency For Generic Drugs Lower Costs For Payers And Patients?" THE BROOKINGS INSTITUTION (June 2017), available at: https://www.brookings.edu/wp·content/uploads/2017/06/es\_20170613\_genericdrugpricing.pdf. (estimating that increasing price transparency in generic drug pricing could reduce health spending by \$4 billion for every \$1 reduction in average reimbursement to retail and mail-order pharmacies); Aaron S. Kesselheim, Jerry Avorn, and Ameet Sarpatwari, "The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform," JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (JAMA), 316(8):858-871 (2016).

<sup>&</sup>lt;sup>7</sup> "California drug pricing transparency bill heads to Gov. Brown," THE MERCURY NEWS, Sept. 13, 2017, available at: http://www.mercurynews.com/2017/09/13/california-drug-pricing-transparency-bill-heads-to-gov-brown/.

contribute to drug manufacturer expenses and list prices and unveil the opaque business practices of pharmacy benefit managers.<sup>8</sup>

At the federal level, U.S. Senators John McCain (R-AZ) and Tammy Baldwin (D-WI) introduced the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act, which would require pharmaceutical corporations that plan to significantly increase drug prices to submit a "transparency and justification" report 30 days before they increase the price of certain drugs that cost at least \$100 by more than 10 percent in one year or 25 percent over three years. The report would require manufacturers to provide a justification for each price increase; manufacturing, research and development costs for the qualifying drug; net profits attributable to the qualifying drug; and marketing and advertising spending on the drug.<sup>9</sup>

The Fund advocated for SB 539's passage in order to help bring transparency to an important part of Nevada's prescription-drug market. (Bond Decl. ¶ 22.) It supported SB 539 with the expectation that mandated disclosure of certain pricing information, along with the law's mandated-disclosure requirements for pharmacy benefit managers, would lead to a more transparent market for diabetes medications in Nevada, help the Fund understand and compare drug prices, and, ultimately, lead to lower privately negotiated drug prices for the Fund and its participants. (*Ibid.*) The Fund's Health Policy Director testified before the Senate Committee on Health & Human Services to highlight the importance of the bill for Fund participants. (*Ibid.*)

SB 539 exempts information that drug manufacturers are required to report to the Nevada Department of Health and Human Services ("DHHS") from Nevada trade-secret protection. The Fund considers this provision crucial to SB 539's functioning and to bringing the benefits of drug-pricing transparency to the Fund and its participants (and

<sup>&</sup>lt;sup>8</sup> "Lowering Drug Costs: Transparency Legislation Sets Off Flurry of New State Approaches," the National Academy for State Health Policy, Aug. 22, 2017, available at: http://www.nashp.org/lowering-drug-costs-transparency-legislation-sets-off-flurry-of-new-state-approaches/.

<sup>&</sup>lt;sup>9</sup> See "McCain & Baldwin Introduce Legislation to Bring Transparency to Prescription Drug Price Increases," May 16, 2017, available at: https://www.mccain.senate.gov/public/index.cfm/2017/5/mccain-baldwin-introduce-legislation-to-bring-transparency-to-prescription-drug-price-increases.

to other private-sector healthcare providers). (Id. at ¶ 23) This exemption is necessary to allow DHHS to publish drug-specific pricing information in its annual report, as Section 4.3 of SB 539 requires DHHS to do, without claims by drug manufacturers that this information is a trade secret in Nevada. (Ibid.) Without public access to drug-specific pricing information, SB 539 will do little to increase transparency in Nevada's diabetesdrug market. (Ibid.) The failure to require public access to drug-pricing information has made Vermont's transparency law—which otherwise shares many features with SB 539—of extremely limited use. The Wall Street Journal reported late last year that, under the Vermont law, "[m]anufacturers were asked to submit all factors that contributed to price increases, and percentages attributable to each factor. But none of their answers are in the report. The 11-page document merely summarizes some of the reasons given, such as the industry's need to invest in research and development." That is because Vermont legislators permitted drug manufacturers to keep their submitted information secret from the public.

Excising SB 539's trade-secret exemption—which PhRMA and BIO wrongly claim

Excising SB 539's trade-secret exemption—which PhRMA and BIO wrongly claim to be constitutionally required—would completely undermine SB 539's promise of a more transparent private market for diabetes drugs.

### **ARGUMENT**

# I. Culinary Health Fund Is Entitled to Intervene as of Right.

Under Federal Rule of Civil Procedure 24(a)(2), an applicant is entitled to intervention of right:

Upon timely application . . . when the applicant claims an interest relating to the property or transaction which is the subject of the action and the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest, unless the applicant's interest is adequately represented by existing parties.

<sup>&</sup>lt;sup>10</sup> Peter Loftus, "Drug Pricing Report Shows Limits of Transparency Push," WALL STREET JOURNAL, Dec. 31, 2016, available at: https://www.wsj.com/articles/drug-pricing-report-shows-limits-of-transparency-push-1483192856.

FED. R. CIV. P. 24(a). The Ninth Circuit broadly construes Rule 24 in favor of applicants 1 for intervention. See United States ex. rel. McGough v. Covington Techs. Co., 967 F.2d 2 3 1391, 1394 (9th Cir. 1992); Donnelly v. Glickman, 159 F.3d 405, 409 (9th Cir. 1998). "A liberal policy in favor of intervention serves both efficient resolution of issues and 4 5 broadened access to the courts. By allowing parties with a practical interest in the outcome of a particular case to intervene, we often prevent or simplify future litigation 6 involving related issues; at the same time, we allow an additional interested party to 7 express its views before the court." Forest Conservation Council v. United States Forest 8

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A. This intervention motion is timely.

Serv., 66 F.3d 1489, 1496 n.8 (9th Cir. 1995) (citation omitted).

This motion is clearly timely. Although SB 539 became law in mid-June, PhRMA and BIO waited two and a half months to file this lawsuit and then another two weeks before seeking a TRO and preliminary injunction. This motion comes just a month after plaintiffs served their lawsuit, three weeks after they filed their preliminary-injunction motion, and a week after the OAG and the Nevada Legislature filed responsive briefs that made clear that intervention was necessary. Courts in the Ninth Circuit regularly hold that intervention motions filed under similar circumstances are timely. See Idaho Farm Bureau Fed'n, 58 F.3d at 1397 (environmental groups' motion to intervene, filed four months after the initial complaint, was timely even though plaintiff had moved for a preliminary injunction); Citizens for Balanced Use, 647 F.3d at 897 ("Applicants filed their motion to intervene in a timely manner, less than three months after the complaint was filed[.]"); W. Expl. LLC v. U.S. Dep't of the Interior, No. 315CV00491MMDVPC, 2016 WL 355122, at \*2 (D. Nev. Jan. 28, 2016) ("Conservation Groups filed their motion to intervene less than two months after Plaintiffs initiated this action and less than a month after Plaintiffs filed their Amended Complaint. There is no question that they have timely moved to intervene.").

PhRMA and BIO may claim that granting the Fund intervention and leave to file its opposition to the preliminary-injunction motion would delay hearing of that motion.

That argument would not be sound. There is sufficient time for plaintiffs to respond to the Fund's opposition brief prior to the October 17 hearing. Even if there were not, any time pressure related to the preliminary-injunction motion is of plaintiffs' making, given their delay in filing suit and seeking injunctive relief.

In the end, such an argument would also fail for the same reason that plaintiffs' preliminary-injunction motion should fail: there is no imminent injury that requires the Court to wrestle with plaintiffs' radical, far-reaching constitutional theories on a compressed timetable. *See Ultra Internet Media, S.A. v. Harrah's License Co., LLC*, No. 2:10CV00455JCMRJJ, 2010 WL 1946666, at \*3 (D. Nev. May 13, 2010) ("The absence of irreparable, *imminent* harm is fatal to a preliminary injunction motion.") (emphasis added).

The crux of plaintiffs' claim for injunctive relief is that their members' pricing information, which they claim is a trade secret in all instances, will lose its Nevada trade-secret protection "as soon as the Department publishes its list of 'essential' diabetes drugs[.]" Plf. Br., Doc. 27, at 22. Plaintiffs believe that a covered drug manufacturer "loses trade-secret protection the moment the Department issues its annual list of 'essential' diabetes drugs, even before the manufacturer actually turns the information over to the State." Complaint, Doc. 1, ¶ 92.

But this misreads the statute. SB 539 amends Nevada's definition of a trade secret to exclude "information that a manufacturer is required to report" pursuant to the Act "to the extent that such information is required to be disclosed by those sections." SB 539, Sec. 9 (amending NRS 600A.030(5)) (emphasis added). That provision is not reasonably read to mean that drug manufacturers lose trade-secret protection over information that they "may be required to report to DHHS many months in the future," as plaintiffs would have it. It means that once a manufacturer has provided a mandated report to DHHS, the contents of the report are not a trade secret (and may not be designated as such), but are instead public information. PhRMA members are not "required to report" any information to DHHS until July 1, 2018, and so information that manufacturers are

"required to report" will not lose trade-secret protection, to the extent it enjoys such protection, until then. See SB 539, Section 26.9(b).

Plaintiffs' obtuse interpretation seems intended to create an artificial sense of urgency, but it does not make sense of the statute. The Fund's opposition papers explain this hole in the injunction motion in more detail. For now, the point is that the Fund's intervention motion is timely under Rule 24(a).

- B. The Fund has protectable interests in this lawsuit that would be impaired if PhRMA and BIO were successful in their challenge to SB 539.
  - 1. The Fund has significant protectable interests in this case.

"An applicant has a 'significant protectable interest' in an action if (1) it asserts an interest that is protected under some law, and (2) there is a 'relationship' between its legally protected interest and the plaintiff's claims." California ex rel. Lockyer v. United States, 450 F.3d 436, 441 (9th Cir. 2006) (quoting Donnelly, 159 F.3d at 409); Sierra Club v. United States EPA, 995 F.2d 1478, 1484 (9th Cir. 1993) ("It is generally enough that the interest [asserted] is protectable under some law, and that there is a relationship between the legally protected interest and the claims at issue."). The "interest" test directs courts to make a "practical, threshold inquiry," Greene v. United States, 996 F.2d 973, 976 (9th Cir. 1993), and "is primarily a practical guide to disposing of lawsuits by involving as many apparently concerned persons as is compatible with efficiency and due process," County of Fresno v. Andrus, 622 F.2d 436, 438 (9th Cir. 1980) (internal quotation marks and citation omitted).

The Fund has significant protectable interests under this definition. As one of the largest private healthcare-benefits providers in the State—with many thousands of participants who rely on affordable diabetes medications—the Fund has a clear interest in defending public access to basic information about how drug manufacturers price their products. (See Bond Decl. ¶¶ 4, 7, 10, 13.) SB 539 requires that manufacturers of

<sup>&</sup>lt;sup>11</sup> The Ninth Circuit has made clear that intervenors do not need to demonstrate Article III standing, most recently in *Vivid Entertainment, LLC v. Fielding*, 774 F.3d 566, 573 (9th Cir. 2014).

essential diabetes drugs submit annual reports to DHHS containing information about the cost of producing the drug, their administrative expenditures (including marketing and advertising) for the drug, their profit on the drug, and the aggregate amount of rebates that the manufacturer has provided to PBMs in Nevada, among other information. SB 539, Section 3.8. If the manufacturer has raised the wholesale acquisition cost of the drug by more than a measure of medical inflation, then the manufacturer is required to explain the factors that led to the price increase. SB 539, Section 4.

SB 539 makes this information public; indeed, this is an important feature of the statute. Each year, DHHS is required to compile a report "on the price of the prescription drugs that appear on the most current lists [of essential diabetes medications], *the reasons for any increases in those prices*, and the effect of those prices on overall spending on prescription drugs in this State." SB 539, Section 4.3. The public report that DHHS must compile includes both the price of each essential diabetes drug and the reasons that manufacturers have given for price increases.

Furthermore, the Legislature exempted all information that "is required to be reported" to DHHS from Nevada trade-secret protection. SB 539, Section 9. This means that affected members of the public, including the Fund, will be able to access the drug manufacturers' reports—including basic information on how manufacturers price essential diabetes drugs—through public-records act requests. See NRS 239.010.

The Fund has an interest in accessing drug manufacturers' information on pricing of specific, essential diabetes drugs, as allowed by SB 539, through public-records act requests and in DHSS's annual public report. Access to this information will allow the Fund to make informed choices about the relative prices of different essential diabetes drugs, what factors contribute to the prices it is paying for these drugs, and (particularly in conjunction with SB 539's PBM-transparency provisions in Section 4.2) whether drugmanufacturer rebates and other price reductions are being passed on to the Fund and its participants. (Bond Decl. ¶¶ 22-24.) This basic information about the market for

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diabetes medications will allow the Fund to make more informed choices in negotiations with PBMs and (ultimately) with drug manufacturers over the prices that the Fund and its participants will pay. (*Id.*  $\P$  24.) Information about long-term price increases particular to diabetes drugs and about the factors that have led to price increases will also allow the Fund to more accurately predict future increases in diabetes medications and to make actuarial decisions accordingly. (*Ibid.*)

The Fund was also a major supporter and proponent of SB 539, as plaintiffs highlight. See Complaint, Doc. 1, at ¶ 35 (citing Fund policy director Bobbette Bond's role in the statute's passage); see also Pls. Br. Supp. Prelim. Inj., Exh. F, Doc. 27-6, ¶ 17 (recognizing the Culinary Union Local 226 "was a major public proponent of SB 539"). Proponents of legislation have a right to intervene to defend the statutes that they proposed and supported. Idaho Farm Bureau Federation v. Babbitt, 58 F.3d 1392, 1397 (9th Cir. 1995) ("A public interest group is entitled as a matter of right to intervene in an action challenging the legality of a measure it has supported."); Prete v. Bradbury, 438 F.3d 949, 954 (9th Cir. 2006) ("[F]or purposes of intervention as of right, a public interest group that has supported a measure (such as an initiative) has a 'significant protectable interest' in defending the legality of the measure.") (quoting Sagebrush Rebellion v. Watt, 713 F.2d 525, 528 (9th Cir. 1983)).

## 2. This lawsuit threatens to impair the Fund's interests in SB 539.

Nor is there any question that this lawsuit threatens to impair the Fund's interests in SB 539 as a practical matter. California ex rel. Lockyer, 450 F.3d at 441. If SB 539's exemption of diabetes drug-pricing information from trade-secret protection were held unconstitutional, then only DHHS and not the Fund or other private healthcare-benefit providers would have access to this information. A key function of the statute that the Fund championed would be undermined: promoting transparency in the private market for essential diabetes drugs.

As explained in more detail in the following section, both the OAG and proposed intervenor Nevada Legislature are taking positions in this litigation that are inconsistent

with SB 539's language and would also undermine the statute's benefits for healthcare providers and consumers. The OAG's responding brief claims that DHHS will "work cooperatively to adopt regulations that may address the concerns about trade secrets and ultimately render them moot." OAG Br., Doc. 37, at 4. It is unclear what regulations the OAG is proposing or how regulations could render plaintiffs' categorical objection to providing SB 539's mandated pricing information moot. The OAG also claims that PhRMA members can sue under the federal Defend Trade Secrets Act (the "DTSA"), 18 U.S.C. § 1836 et seq., to prevent DHHS's publication or release of information they believe is trade-secret protected, even though the DTSA has an express anti-preemption provision, 18 U.S.C. § 1838, and does "not prohibit or create a private right of action for any otherwise lawful activity conducted by a government entity of the United States, a State or political subdivision of a State." 18 U.S.C. § 1833(a)(1).

Legislative Counsel Bureau, for its part, takes the untenable position that SB 539 does not require any drug manufacturer to submit information to DHHS that the drug manufacturer claims as trade-secret protected, even though there would be no point to exempting such information from Nevada's trade-secret law if this were so. *See* Nev. Legis. Br., Doc. 42, at 9-11.

The Fund's protectable interests in this litigation are threatened not only by the plaintiffs who are challenging SB 539's constitutionality, but also by the government representatives charged with defending it.

# C. The Fund is not adequately represented by the Office of the Attorney General or the Legislative Counsel Bureau.

The Fund's interests in this lawsuit are not adequately represented by the existing government defendants—Governor Sandoval and DHHS Director Richard Whitley. Nor are they adequately protected by intervenor Nevada Legislature. This is so for two reasons: (1) the Fund has narrower and more "parochial" interests in this litigation than do DHHS or the Nevada Legislature; and (2) both the OAG and the Legislative Counsel Bureau are taking positions in this litigation that would undermine key protections in the

statute and are contrary to those the Fund seeks to present. The Court should allow the Fund's intervention so that it is presented with a full constitutional defense of the statute as it was drafted and adopted.

Regardless of whether the government is an existing party or whether the movant's and the government's interests are generally aligned, an intervenor is required to show only that existing parties "may" inadequately represent its interests, a showing that the Supreme Court and Ninth Circuit describe as "minimal." *Berg*, 268 F.3d at 823 ("[T]he burden of showing inadequacy is 'minimal,' and the applicant need only show that representation of its interests by existing parties 'may be' inadequate."). This standard was set forth in *Trbovich v. United Mine Workers of America*, 404 U.S. 528, 538 n.10 (1972). In that case, the Court held that a union member could intervene in an action by the Secretary of Labor to set aside a union election—the same outcome that the union member sought to achieve—despite the fact that the Secretary of Labor was representing the union member's interests. The Court reversed a district court denial of intervention, holding that "even if the Secretary is performing his duties, broadly conceived, as well as can be expected, the union member may have a valid complaint about the performance of 'his lawyer." *Id.* at 539.

The Ninth Circuit has repeatedly held that this lenient standard applies in cases in which the government is an existing party. See, e.g., Berg, 268 F.3d at 823; Citizens for Balanced Use v. Montana Wilderness Ass'n, 647 F.3d 893, 900 (9th Cir. 2011); Prete v. Bradbury, 438 F.3d 949, 959 (9th Cir. 2006) ("emphasiz[ing] . . . that the burden of showing inadequacy of representation is generally minimal" but finding that the proposed intervenor had not met its burden because it had not shown that the government had taken positions that were markedly different from those the intervenor would take).

# 1. The Fund's interests in this lawsuit differ from those of the government.

Although the Ninth Circuit applies a rebuttable presumption that a government defendant will adequately protect a proposed intervenor's interests, this presumption is overcome when the proposed intervenor has interests in the litigation that are different

(intervenor met its burden of showing inadequate representation when government was "required to represent a broader view than the more narrow, parochial interests" of the intervenor); California, ex rel. Bill Lockyer, 450 F.3d at 445 (proposed intervenors overcame presumption of showing government would adequately represent their interests when intervenors had "more narrow, parochial interests"). Moreover, the mere fact that a proposed intervenor and the government share the same general objective—such as upholding a law's validity—does not stand as a barrier to intervention if the proposed intervenor represents interests that are narrower than those of the general public. Citizens for Balanced Use, 647 F.3d at 899 ("As one of our sister circuits has persuasively explained, the government's representation of the public interest may not be 'identical to the individual parochial interest' of a particular group just because 'both entities occupy the same posture in the litigation.") (internal citation omitted).

Thus, unions seeking to defend the validity of laws that benefit their members are regularly granted intervention, even with a government defendant. See, e.g., Californians for Safe & Competitive Dump Truck Trans. v. Mendonca, 152 F.3d 1184, 1190 (9th Cir. 1998) ("[B]ecause employment interests of [union's] members were potentially more narrow and parochial than the interests of the public at large, [union] demonstrated that the representation of its interests by [the state] may have been inadequate"); Golden Gate Restaurant Ass'n v. City & County of San Francisco, No. 06-06997, 2007 WL 1052820 (N.D. Cal. April 5, 2007); Am. Hotel & Lodging Ass'n v. City of Los Angeles, No. CV 14-09603-AB (SSX), 2015 WL 12745805, at \*1 (C.D. Cal. Mar. 25, 2015).

Similarly, industry groups are regularly granted intervention to defend their more narrow interest in legislation or official action that has been challenged. See, e.g., Berg, 268 F.3d at 814 (four national building contractor associations granted intervention of right to defend city's action over Endangered Species Act challenge); New York Public Interest Research Group v. Regents of University of State of N.Y., 516 F.2d 350, 351-52 (2nd Cir. 1975) (reversing district court's denial of a motion to intervene by a pharmacists

organization seeking to bolster the state's defense of a regulation banning advertising of prescription-drug prices).

Here, the Fund has a narrow interest—as a healthcare benefit provider, retail pharmacy, and medical provider—in preserving the right of *public* access to drug manufacturers' pricing information. Access to this information is important to the Fund's ability to understand the private market for essential diabetes drugs and to negotiate privately with and through PBMs for lower drug prices. (*See* generally Bond Decl. at ¶¶ 16-18 & 22-24.) The Fund's narrow interest in maintaining public access to the pricing information that drug manufacturers are required to submit to DHHS is not shared by the government or by the general public. Both the OAG and the Legislative Counsel Bureau have made clear that they are willing to trade away the trade-secret exemption contained in SB 539, based on some political or legal calculus that is unclear to the Fund.

# 2. The OAG and Legislature are taking positions that would eviscerate key protections in SB 539.

The Ninth Circuit has "recognized that willingness to suggest a limiting construction in defense of a statute is an important consideration in determining whether the government will adequately represent its constituents' interests." *California ex rel. Lockyer*, 450 F.3d at 444. Both the OAG and the Legislative Counsel Bureau have taken positions that would undermine SB 539's trade-secret exemption and the promise of public access to diabetes drug-pricing information.

In *California ex rel. Lockyer*, healthcare providers that were religiously opposed to providing abortion services sought to intervene on the side of the federal government in California's Fifth and Tenth Amendment challenge to the constitutionality of the Weldon Amendment, a budget appropriations rider that prohibited states from receiving certain federal funds if they discriminated against healthcare providers who refused to perform or pay for abortions. The federal government offered a limiting construction of the Weldon Amendment, arguing that it only prohibited facial discrimination against healthcare providers who refused to perform abortions, but did not reach California

Health & Safety Code § 1317, which prohibits healthcare providers from refusing to perform *any* emergency healthcare service, not just emergency abortions. This limiting construction, however, was "direct evidence that the United States will take a position that actually compromises (and potentially eviscerates) the protections of the Weldon Amendment" for the proposed intervenors. *Id.* at 445. On this basis, the Ninth Circuit found that the government did not adequately represent the religious healthcare providers' interests.

Here, both the OAG and the Legislative Counsel Bureau have presented interpretations of SB 539—and offered positions on permissible DHHS regulations—that would "compromise and potentially eviscerate" key provisions of the statute.

The OAG argues that "Nevada's state law protection [of trade secrets] appears to be redundant" to the federal Defend Trade Secrets Act ("DTSA"), 18 U.S.C. § 1836 et seq., and suggests that this federal statute prohibits DHHS from releasing drug-pricing information to the public. OAG Br., at 5-6. The OAG further suggests that DHHS will adopt regulations that "may be able to ensure a process to protect trade secrets as defined by DTSA" and that "the manufacturers and the Department [will] work cooperatively to adopt regulations that may address the concerns about trade secrets and ultimately render them moot." *Id.* at 4.

But these concessions and the OAG's interpretation of the DTSA are misplaced. Federal trade-secret law, including the DTSA, does "not prohibit or create a private right of action for any otherwise lawful activity conducted by a government entity of the United States, a State or political subdivision of a State." 18 U.S.C. § 1833(a)(1). The DTSA cannot be used to prohibit the Nevada government from releasing information to the public when this course of action is fully consistent with—and in fact is mandated by—Nevada law. Moreover, the DTSA itself contains an express anti-preemption provision, 18 U.S.C. § 1838, further demonstrating that it was not intended to displace state-law limitations on the definition of trade secrets.

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The Legislative Counsel Bureau is even more brazen in its attempt to rewrite the statute. It claims that "based on the plain language of the challenged provisions, manufacturers can satisfy their disclosure requirements with carefully drafted reports which provide the necessary business information to NDHHS but which do not reveal information that constitutes a *trade secret*." Nev. Legis. Br., Doc. 42, at 6. It goes on to invite drug manufacturers to "enter[] into confidentiality agreements with NDHHS to protect trade-secret information provided in their reports" so that the contents do not have to be released to the public. *Id.* at 9.

But these positions make no sense in light of SB 539's express exemption of information that drug manufacturers are required to report to DHHS from trade-secret protection. If SB 539 did not require drug manufacturers to submit any information that they might consider a trade secret, then what was the point of exempting that information from state trade-secret protection?<sup>12</sup> The answer that the Legislative Counsel Bureau gives is untenable. It claims that SB 539 exempted drug-pricing information from trade-secret protection only in instances in which a drug manufacturer neglected to mark the submitted information as confidential or trade-secret protected: "if manufacturers provide trade-secret information in their reports to NDHHS without undertaking the proper means to protect the trade-secret information from disclosure, that information would lose its protected trade-secret status because of the manufacturers' own failure to undertake reasonable efforts to protect its secrecy." Nev. Legis. Br., Doc. 42, at 10-11.

SB 539 contains no such limitation to its trade-secret exemption, and such a rule would be unnecessary, since it is already the law that information submitted to the government without attempts to safeguard the information's confidentiality loses any

<sup>&</sup>lt;sup>12</sup> This is not to say that all of the information that SB 539 requires manufacturers to report is necessarily a trade secret. The Fund agrees with the Nevada Legislature that determinations of whether business pricing information is a trade secret occur on a case-by-case basis. *See Franz v. Johnson*, 116 Nev. 455, 466–67 (2000) ("[T]he determination of whether corporate information, such as customer and pricing information, is a trade secret is a question for the finder of fact" and "not every customer and pricing list will be protected as a trade secret.").

potential trade-secret protection. See, e.g., Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1002 (1984) ("If an individual discloses his trade secret to others who are under no obligation to protect the confidentiality of the information, or otherwise publicly discloses the secret, his property right is extinguished."); Masonite Corp. v. Cty. of Mendocino Air Quality Mgmt. Dist., 42 Cal.App.4th 436, 455 (1996) ("Once the . . . information was submitted in the reports without trade secret designation, whether deliberately or inadvertently, it was a public record which the [public agency], and others, could disclose without restriction to the public generally. Lost was the essential character of the information as a trade secret.").

As the Fund explains in its opposition to plaintiffs' preliminary-injunction motion, these concessions and untenable limiting constructions are unnecessary. Plaintiffs' readings of federal patent law, the DTSA, and takings and dormant commerce clause jurisprudence are radical and, ultimately, baseless. The Court is not required to address the merits of the OAG's or Legislative Counsel Bureau's readings of SB 539 for purposes of this intervention motion; it is enough that both seek to have the Court interpret the law in ways that would undermine the Fund's interest in SB 539.

Aside from the OAG's call to eviscerate the public access to drug-pricing information that SB 539 promises, it has demonstrated an unwillingness or inability to respond to plaintiffs' legal arguments. In assessing adequacy of representation, the Ninth Circuit considers "whether the [government] will undoubtedly make all of the intervenor's arguments, whether the [government] is capable of and willing to make such arguments, and whether the intervenor offers a necessary element to the proceedings that would be neglected." *Sagebrush Rebellion*, 713 F.2d at 528.

In response to plaintiffs' twenty-four page brief in support of a preliminary injunction, the OAG filed a five-and-a-half page brief that cites only a single court case (on a collateral point), does not address the merits of plaintiffs' legal claims in any meaningful way, and merely asks that "any preliminary injunction should be narrowly tailored to enjoin the enforcement and implementation of the specific parts of the state

legislation which this Court finds will result in irreparable harm related to the trade 1 secrets of Plaintiffs." OAG Br., Doc. 37, at 2. This is hardly the "full and vigorous 2 defense of [SB 539's] constitutionality" that could demonstrate that the OAG is 3 adequately representing the Fund's interests. Cf. Perry v. Proposition 8 Official 4 5 Proponents, 587 F.3d 947, 954 (9th Cir. 2009). II. If It Is Denied Intervention of Right, the Fund Should Be Granted Intervention on 6 a Permissive Basis. 7 If the Court for some reason determines that the Fund is not entitled to intervene 8

If the Court for some reason determines that the Fund is not entitled to intervene in this lawsuit as a matter of right, it should grant the Fund intervention on a permissive basis under Federal Rule of Civil Procedure 24(b). Generally, "[a]n applicant who seeks permissive intervention must prove that it meets three threshold requirements: (1) it shares a common question of law or fact with the main action; (2) its motion is timely; and (3) the court has an independent basis for jurisdiction over the applicant's claims. Donnelly, 159 F.3d at 412. However, where, as here "the proposed intervenor in a federal-question case brings no new claims, the jurisdictional concern drops away." Freedom from Religion Found., Inc. v. Geithner, 644 F.3d 836, 844 (9th Cir. 2011).

For the reasons stated above, the Fund's motion is timely. The Fund's interest in this case also shares common questions of law and fact with plaintiffs' action, namely the facial constitutionality of SB 539. Permissive intervention is therefore appropriate.

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### CONCLUSION

For the foregoing reasons, the Culinary Health Fund should be granted intervention in this lawsuit as a party defendant and given leave to file its brief in opposition to plaintiffs' request for injunctive relief. If the Court for some reason determines that leave to file the opposition brief as an intervenor is not appropriate, the Court should consider the Fund's opposition as a brief *amicus curiae*.

Dated: October 6, 2017 Respectfully submitted,

McCRACKEN, STEMERMAN & HOLSBERRY, LLP

By: <u>/s/Paul L. More</u> Paul L. More

Attorneys for Culinary Health Fund

# Index to Exhibits

Exhibit Number	Description	
1	Culinary Health Fund's Answer to Complaint for Declaratory and Injunctive Relief	

1	Richard G. McCracken (Nevada Bar No. 2748)		
2	Paul L. More (Nevada Bar No. 9628)		
_	Sarah Grossman-Swenson (Nevada Bar No. 11979)		
3	McCRACKEN, STEMERMAN & HOLSBERRY, LLP		
4	1630 Commerce Street, Suite A-1		
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6	Email: rmccracken@msh.law		
	pmore@msh.law		
7	sgs@msh.law		
8			
9	Attorneys for Culinary Health Fund		
10	UNITED STATES DISTRICT COURT		
	DISTRICT OF NEVADA		
11			
12	PHARMACEUTICAL RESEARCH AND	CASE NO. 2:17-cv-02315-JCM-CWH	
	MANUFACTURERS OF AMERICA; and		
13	BIOTECHNOLOGY INNOVATION		
14	ORGANIZATION,		
15	DI : 4:66	CULINARY HEALTH FUND'S	
	Plaintiff,	ANSWER TO COMPLAINT FOR DECLARATORY AND INJUNCTIVE	
16	vs.	RELIEF	
17		16BHET	
	BRIAN SANDOVAL, in his official capacity		
18	as Governor of the State of Nevada;		
19	RICHARD WHITLEY, in his official		
	capacity as Director of the Nevada		
20	Department for Health and Human		
21	Services; and the NEVADA LEGISLATURE,		
,	LEGISLATORE,		
22	Defendants.		
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Stemerman & Holsberry LLP, answers plaintiffs' complaint in this action as follows:

or legal conclusions that the Fund is not required to answer, but that it nonetheless

or legal conclusions that the Fund is not required to answer, but that it nonetheless

Culinary Health Fund (the "Fund"), through its counsel of record McCracken,

Answering paragraph 1, this paragraph contains opinions, argument,

Answering paragraph 2, this paragraph contains opinions, argument,

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denies.

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denies. The Fund admits the Nevada recently enacted Senate Bill 539.

- 4. Answering paragraph 4, this paragraph contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 5. Answering paragraph 5, this paragraph contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 6. Answering paragraph 6, this paragraph contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 7. Answering paragraph 7, this paragraph contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 8. Answering paragraph 4, this paragraph contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies. The Fund admits that Governor Brian Sandoval vetoed Senate Bill 265, but denies the complaint's characterization of his reasons for doing so.

- 9. The Fund admits that the quoted excerpts from Governor Sandoval's veto letter are accurately quoted, but denies all other allegations contained in paragraph 9.
- 10. Answering paragraph 10, this paragraph contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 11. The Fund is without sufficient information to affirm or deny the allegations contained in paragraph 11, and therefore denies the same.
- 12. The Fund is without sufficient information to affirm or deny the allegations contained in paragraph 12, and therefore denies the same.
- 13. The Fund admits the allegations contained in paragraph 13, except the characterization that Governor Sandoval is responsible for the "execution" of SB 539, which the Fund denies.
  - 14. The Fund admits the allegations contained in paragraph 14.
- 15. Paragraph 15 states a legal conclusion that the Fund is not required to answer, and therefore the Fund denies the same.
- 16. Paragraph 16 states a legal conclusion that the Fund is not required to answer, and therefore the Fund denies the same.
- 17. Paragraph 17 states a legal conclusion that the Fund is not required to answer, and therefore the Fund denies the same.
  - 18. The Fund admits the allegations contained in Paragraph 18.
  - 19. The Fund admits the allegations contained in Paragraph 19.
  - 20. The Fund admits the allegations contained in Paragraph 20.
  - 21. The Fund admits the allegations contained in Paragraph 21.
  - 22. The Fund admits the allegations contained in Paragraph 22.
- 23. Paragraph 23 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains

allegations that are not opinion, argument or legal conclusion, the Fund is without sufficient information to affirm or deny those allegations, and therefore denies the same.

- 24. Paragraph 24 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without sufficient information to affirm or deny those allegations, and therefore denies the same.
- 25. The Fund admits the first sentence of Paragraph 25. The remainder of Paragraph 25 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without sufficient information to affirm or deny those allegations, and therefore denies the same.
- 26. Paragraph 26 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without sufficient information to affirm or deny those allegations, and therefore denies the same.
- 27. Paragraph 27 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without sufficient information to affirm or deny those allegations, and therefore denies the same.
- 28. Paragraph 28 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without

sufficient information to affirm or deny those allegations, and therefore denies the same.

- 29. Paragraph 29 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without sufficient information to affirm or deny those allegations, and therefore denies the same.
- 30. Paragraph 30 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without sufficient information to affirm or deny those allegations, and therefore denies the same.
- 31. Paragraph 31 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without sufficient information to affirm or deny those allegations, and therefore denies the same.
- 32. Paragraph 32 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without sufficient information to affirm or deny those allegations contained, and therefore denies the same.
  - 33. The Fund admits the allegations contained in Paragraph 33.
- 34. The Fund admits that SB 265 was introduced in the Nevada Senate in February 2017. The Fund denies the remaining allegations in Paragraph 34.

- 35. The Fund admits that the portions of testimony from hearings on SB 265 are accurately quoted. The Fund denies all other allegations contained in Paragraph 35.
- 36. Paragraph 36 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 265 speaks for itself and therefore denies the characterizations of SB 265 contained in Paragraph 36.
- 37. Paragraph 37 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 539 speaks for itself and therefore denies the characterizations of SB 539 contained in Paragraph 36.
  - 38. The Fund admits the allegations contained in Paragraph 38.
- 39. The Fund admits the first sentence in Paragraph 39. The Fund admits that the portions of Governor Sandoval's veto letter are accurately quoted. The Fund denies all other allegations and characterizations contained in Paragraph 39.
- 40. The Fund admits that the portions of Governor Sandoval's veto letter are accurately quoted. The Fund denies all other allegations and characterizations contained in Paragraph 40.
- 41. The Fund admits that the Nevada Senate and Nevada State Assembly passed SB 539 on June 5, 2017. The remainder of Paragraph 41 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 539 speaks for itself and therefore denies the characterizations of SB 539 contained in Paragraph 41.

- 42. The Fund admits that Governor Sandoval signed SB 539 on June 15, 2017, but denies all other allegations in Paragraph 42.
- 43. Paragraph 43 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 539 speaks for itself and therefore denies the characterizations of SB 539 contained in Paragraph 43.
  - 44. The Fund admits the allegations in Paragraph 44.
- 45. Paragraph 45 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 539 speaks for itself and therefore denies the characterizations of SB 539 contained in Paragraph 45.
- 46. Paragraph 46 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 539 speaks for itself and therefore denies the characterizations of SB 539 contained in Paragraph 46.
- 47. The Fund is without sufficient information to affirm or deny the allegations contained in Paragraph 47, and therefore denies the same.
  - 48. The Fund denies the allegations contained in Paragraph 48.
- 49. Paragraph 49 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 539 speaks for itself and therefore denies the characterizations of SB 539 contained in Paragraph 49.

- 50. Paragraph 50 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 539 speaks for itself and therefore denies the characterizations of SB 539 contained in Paragraph 50.
- 51. Paragraph 51 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 539 speaks for itself and therefore denies the characterizations of SB 539 contained in Paragraph 51.
- 52. Paragraph 52 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 539 speaks for itself and therefore denies the characterizations of SB 539 contained in Paragraph 52.
- 53. Paragraph 53 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 539 speaks for itself and therefore denies the characterizations of SB 539 contained in Paragraph 53.
- 54. Paragraph 54 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 539 speaks for itself and therefore denies the characterizations of SB 539 contained in Paragraph 54. The Fund is without sufficient information to affirm or deny that the Department has represented that it intends to publish the list on October 15, 2017, and therefore denies the same.

- 55. The Fund denies the first sentence of Paragraph 55. The Fund is without sufficient information to affirm or deny the remaining allegations in Paragraph 55, and therefore denies the same.
- 56. Paragraph 56 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without sufficient information to affirm or deny those allegations, and therefore denies the same.
- 57. Paragraph 57 contain opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without sufficient information to affirm or deny those allegations, and therefore denies the same.
- 58. Paragraph 58 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without sufficient information to affirm or deny those allegations, and therefore denies the same.
- 59. Paragraph 59 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without sufficient information to affirm or deny those allegations, and therefore denies the same.
- 60. Paragraph 60 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without

sufficient information to affirm or deny those allegations, and therefore denies the same.

- 61. The first sentence of Paragraph 61 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the first sentence of the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 539 speaks for itself and therefore denies the characterizations of SB 539 contained in that sentence. The Fund denies the allegations in the second sentence of Paragraph 61.
- 62. Paragraph 62 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 539 speaks for itself and therefore denies the characterizations of SB 539 contained in Paragraph 62.
- 63. Paragraph 63 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without sufficient information to affirm or deny those allegations, and therefore denies the same.
- 64. Paragraph 64 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without sufficient information to affirm or deny those allegations, and therefore denies the same.
- 65. Paragraph 65 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without

sufficient information to affirm or deny those allegations, and therefore denies the same.

- 66. Paragraph 66 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without sufficient information to affirm or deny those allegations, and therefore denies the same.
- 67. Paragraph 66 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund is without sufficient information to affirm or deny those allegations, and therefore denies the same.
- 68. Paragraph 68 contain opinions, argument, or legal conclusions that the Fund is not required to answer.
- 69. Paragraph 69 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 70. Paragraph 70 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 71. Paragraph 71 contain opinions, argument, or legal conclusions that the Fund is not required to answer.
- 72. Paragraph 72 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 73. Paragraph 73 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 74. Paragraph 74 contains opinions, argument, or legal conclusions that the Fund is not required to answer.

- 75. Paragraph 75 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 76. Paragraph 76 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 77. Paragraph 77 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 539 speaks for itself and therefore denies the characterizations of SB 539 contained in Paragraph 77.
- 78. Paragraph 78 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 539 speaks for itself and therefore denies the characterizations of SB 539 contained in Paragraph 78.
- 79. Paragraph 79 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 80. Paragraph 80 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 81. Paragraph 81 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies. The Fund admits that the portion of the March 29 hearing minutes are accurately quoted, but denies all other allegations and characterizations of the Nevada Legislature's action contained in Paragraph 81.
- 82. Paragraph 82 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 83. Paragraph 83 contains opinions, argument, or legal conclusions that the Fund is not required to answer.

- 84. Paragraph 84 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 85. Paragraph 85 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 86. Paragraph 86 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 87. Paragraph 87 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 88. Paragraph 88 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 89. Paragraph 89 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 90. Paragraph 90 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 91. Paragraph 90 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 92. The first sentence of Paragraph 92 contains opinions, argument, or legal conclusions that the Fund is not required to answer. To the extent that the first sentence of Paragraph 92 contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 539 speaks for itself and therefore denies the characterizations of SB 539 contained in that sentence. The Fund denies the allegations contained in the second sentence of Paragraph 92.
- 93. Paragraph 93 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies. To the extent that the paragraph contains allegations that are not opinion, argument or legal conclusion, the Fund avers that the language of SB 539 speaks for itself and therefore denies the characterizations of SB 539 contained in Paragraph 93.

- 94. Paragraph 94 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 95. Paragraph 95 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 96. Paragraph 96 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 97. Paragraph 97 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 98. Paragraph 98 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 99. Paragraph 99 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 100. Paragraph 100 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 101. Paragraph 101 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 102. Paragraph 102 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 103. Paragraph 103 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 104. Paragraph 104 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 105. Paragraph 105 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 106. Paragraph 106 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.

- 107. Paragraph 107 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 108. Paragraph 108 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 109. Paragraph 109 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 110. Paragraph 110 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 111. Paragraph 111 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 112. Paragraph 112 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 113. Paragraph 113 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 114. Paragraph 114 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 115. Paragraph 115 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 116. Paragraph 116 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 117. The Fund re-alleges and incorporates by reference all prior and subsequent answering paragraphs.
- 118. Paragraph 118 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 119. Paragraph 119 contains opinions, argument, or legal conclusions that the Fund is not required to answer.

- 120. Paragraph 120 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 121. Paragraph 121 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 122. The Fund re-alleges and incorporates by reference all prior and subsequent answering paragraphs.
- 123. Paragraph 123 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 124. Paragraph 124 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 125. Paragraph 125 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 126. The Fund re-alleges and incorporates by reference all prior and subsequent answering paragraphs.
- 127. Paragraph 127 contains opinions, argument, or legal conclusions that the Fund is not required to answer.
- 128. Paragraph 128 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 129. Paragraph 129 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 130. Paragraph 130 contains opinions, argument, or legal conclusions that the Fund is not required to answer, but that it nonetheless denies.
- 131. The Fund re-alleges and incorporates by reference all prior and subsequent answering paragraphs.
- 132. Paragraph 132 contains opinions, argument, or legal conclusions that the Fund is not required to answer.

1 Paragraph 133 contains opinions, argument, or legal conclusions that 2 the Fund is not required to answer, but that it nonetheless denies. FIRST AFFIRMATIVE DEFENSE 3 The complaint fails to state a claim upon which relief can be granted. 4 5 SECOND AFFIRMATIVE DEFENSE Plaintiffs have failed to join all necessary parties who are needed for a just 6 7 adjudication. THIRD AFFIRMATIVE DEFENSE 8 Plaintiffs lack standing, associational or otherwise, to bring this action. 9 FOURTH AFFIRMATIVE DEFENSE 10 11 Plaintiffs' claims are not ripe for adjudication, or otherwise do not present a 12 justiciable case or controversy. FIFTH AFFIRMATIVE DEFENSE 13 14 Plaintiffs' claims for injunctive relief are barred under the doctrine of laches. The Fund reserves the right to amend this answer to assert any applicable, 15 additional or other defenses constituting an affirmative defense at such time as the 16 17 nature of plaintiffs' claims and the alleged facts relating to those claims are revealed to the Fund. 18 19 Dated: October 6, 2017 Respectfully submitted, 20 21 McCRACKEN, STEMERMAN & 22 HOLSBERRY, LLP 23 24 By: /s/Paul More Paul L. More 25 26 Attorneys for Culinary Health Fund 27 28